7/24/98

DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

T1935M

PHILADELPHIA DISTRICT
900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106
Telephone: 215-[redacted]

WARNING LETTER

GEN.
RELEASE
F# - DATE 7/20/98
Reviewed by: [redacted]

July 20, 1998

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Max L. Mendelsohn, President and Chief Executive Officer
Global Pharmaceutical Corporation
Castor & Kensington Avenues
Philadelphia, PA 19124-5694

Dear Mr. Mendelsohn:

On April 7, 1998, Philadelphia District Investigator Susan F. Laska and Center for Veterinary Medicine Consumer Safety Officer Michael R. Talley, DVM, visited your pharmaceutical manufacturing facility and conducted an inspection regarding your firm's distribution of methyltestosterone tablets. On April 8, 1998, we received via facsimile from Marc M. Feinberg, Vice President of Quality and Regulatory Affairs, a copy of the Agreement Between [redacted] and Global Pharmaceutical Corporation (Global).

The inspection revealed that methyltestosterone tablets supplied to [redacted] are labeled for use in humans, consistent with Global's approved abbreviated new drug applications (ANDA) for this product. However, the sales agreement between [redacted] and Global specifically states that [redacted] agrees to be Global's exclusive distributor of methyltestosterone for the greyhound canine market and that [redacted] will sell the methyltestosterone tablets supplied under this agreement exclusively to the greyhound canine market and not for human consumption. This agreement constitutes an intended use, as described in Title 21 Code of Federal Regulations (21 CFR) § 201.128, of an approved human drug in dogs. Consequently, methyltestosterone supplied to [redacted] is misbranded within the meaning of Section 502(f)(1) of the Federal Food, Drug, and Cosmetic (FD&C) Act in that its labeling fails to bear adequate directions for the use for which the drug is intended under this sales agreement. Additionally, 21 CFR § 201.198 requires that Global, as the drug product manufacturer with prior knowledge -- as evidenced by the sales agreement -- of [redacted] intended use of the methyltestosterone tablets, provide adequate labeling for this intended use. Adequate directions for veterinary use cannot be written because this product has not been shown to be safe and effective for

veterinary use through approved new animal drug application filed pursuant to Section 521(a)(1) of the Act.

The above is not intended to be an all-inclusive list of deficiencies at your firm. As top management, it is your responsibility to assure that all of your company's operations are in compliance with the FD&C Act and its associated regulations.

Federal agencies are advised of the issuance-of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts. In addition, pending new drug applications (NDA's), abbreviated new drug applications (ANDA's), or export approval requests may not be approved until the aforementioned violations are corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please advise this office in writing within fifteen (15) days of receipt of this letter as to the specific actions you have taken or intend to take to correct these violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which corrections will be completed. Your reply should be addressed to Karyn M. Campbell, Compliance Officer, at the address noted on the letterhead.

Sincerely,

John W. Thorsky
Acting District Director
Philadelphia District Office

cc: Robert E. Bastian, Director
Division of Primary Care and Home Health Services
PA Department of Health
132 Kline Plaza, Suite A
Harrisburg, PA 17104